Correction to Table IV-8 in the Addendum to the
***In Vitro* Ocular Toxicity Draft Background Review Documents**

Review of data presented in **Table IV-8** of the Addendum indicated that there were errors in the false negative and false positive rates presented for the physical form analysis (under properties of interest). The attached revised **Table IV-8** contains the corrected results (noted in bold). This revised table and the accompanying text should be used in place of the table and lines 3012 to 3016 in the released Addendum.

Table IV-8. False Negative and False Positive Rates of the HET-CAM Test Method, by Chemical Class and Properties of Interest, for the GHS[1] Classification System

Category	N[2]	False Positive Rate[3]		False Negative Rate[3]	
		%	No.	%	No.
Overall IS(B)-10 (Entire database)	101	33	20/61	30	12/40
Overall IS(B)-100 (Entire database)	143	60	61/102	15	6/41
Chemical Class[4]-IS(B)-10					
Alcohol	17	90	9/10	25	2/7
Amine	7	60	3/5	50	1/2
Ether	14	50	5/10	50	2/4
Formulation	24	0	0/8	44	7/16
Heterocycle	6	83	5/6	-	-
Organic salt	7	57	4/7	-	-
Chemical Class[4]-IS(B)-100					
Alcohol	20	91	10/11	11	1/9
Aldehyde	6	80	4/5	0	0/1
Amine	10	83	5/6	50	2/4
Ester	14	83	10/12	0	0/2
Ether	20	60	9/15	20	1/5
Formulation	51	19	6/31	35	7/13
Heterocycle	10	75	6/8	-	-
Inorganic salt	5	100	2/2	0	0/3
Ketone	6	67	4/6	-	-
Onium	7	100	2/2	0	0/5
Organic salt	8	88	7/8	-	-
Properties of Interest					
Physical Form: IS(B)-10					
Liquid	**101**	**33**	**20/61**	**30**	**12/40**
Solid	-	-	-	-	-
Physical Form: IS(B)-100					
Liquid	**63**	**67**	**36/54**	**0**	**0/9**
Solid	**43**	**67**	**16/24**	**26**	**5/19**
Unknown	**37**	**38**	**9/24**	**8**	**1/13**
Surfactant – Total IS(B)-100	3	66	2/3	-	-
-nonionic	3	66	2/3	-	-
-anionic	0	-	-	-	-
-cationic	0	-	-	-	-
Surfactant-Based Formulation – IS(B)-10	24	0	0/8	44	7/16
pH – IS(B)-10[5]	35	58	11/19	13	2/16
- acidic (pH < 7.0)	24	50	7/14	20	2/10
- basic (pH > 7.0)	11	80	4/5	0	0/6
pH – IS(B)-100[5]	35	68	13/19	13	2/16
- acidic (pH < 7.0)	23	69	9/13	10	1/10
- basic (pH > 7.0)	12	67	4/6	17	1/6

Category	N[2]	False Positive Rate[3]		False Negative Rate[3]	
		%	No.	%	No.
Category 1 Subgroup-IS(B)-10[6]					
- Total	40	-	-	30	12/40
- 4 (CO=4 at any time)	13	-	-	15	2/13
- 3 (severity/persistence)	0	-	-	-	-
- 2 (severity)	0	-	-	-	-
- 2-4 combined[7]	*13*	-	-	15	2/11
- 1 (persistence)	27	-	-	37	10/27
Category 1 Subgroup-IS(B)-100[6]					
- Total	37	-	-	11	4/37
- 4 (CO=4 at any time)	19	-	-	11	2/19
- 3 (severity/persistence)	2	-	-	0	0/2
- 2 (severity)	2	-	-	0	0/2
- 2-4 combined[7]	*23*	-	-	9	2/23
- 1 (persistence)	18	-	-	11	2/18

[1]GHS = Globally Harmonized System (UN [2003]).
[2]N=number of substances
[3]False Positive Rate = the proportion of all negative substances that are falsely identified as positive in vitro; n = number of substances; False Negative Rate = the proportion of all positive substances that are falsely identified as negative in vitro.
[4]Chemical classes included in this table are represented by at least five substances tested in the HET-CAM test method and assignments are based on the MeSH categories (www.nlm.nih.gov/mesh). See **Appendix B**.
[5]Total number of GHS Category 1 substances for which pH information was obtained.
[6]NICEATM-defined subgroups assigned based on the lesions that drove classification of a GHS Category 1 substance. 1: based on lesions that are persistent; 2: based on lesions that are severe (not including Corneal Opacity [CO]=4); 3: based on lesions that are severe (not including CO=4) and persistent; 4: CO = 4 at any time.
[7]Subcategories 2 to 4 combined to allow for a direct comparison of GHS Category 1 substances classified *in vivo* based on some lesion severity component and those classified based on persistent lesions alone.

Text to be used in place of lines 3012 to 3016:

With regard to physical form of the substances overpredicted by the IS(B)-10 analysis method, the false positive and false negative rates were 33% (20/61) and 30% (12/40), respectively for liquids. Since only diluted chemicals were tested for the IS(B)-10 analysis method, there were no solids to evaluate for this analysis method. For the IS(B)-100 analysis method liquids and solids had the same false positive rate (67%; 36/54 and 16/24, respectively), but solids had a higher false negative rate (see **Table IV-8**).